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10/568,258

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Thomas J. Borody

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ATLANTA, GA 30309-3915

EXAMINER

HAWTHORNE, OPHELIA ALTHEA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/568,258 | Applicant(s) BORODY, THOMAS J. | |
| | Examiner OPHELIA HAWTHORNE | Art Unit 4148 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>13 February 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 22 – 24** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 22 – 24, the claims does not put forth any method steps; therefore, it is unclear whether applicant is claiming a method or an apparatus.

3. **Claims 25 – 27** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1 – 14, 17 - 18 & 21 – 27** are rejected under 35 U.S.C. 102(e) as being anticipated by **Hickle Pub No. (US 2004/0129273 A1)**.

Regarding claim 1, Hickle discloses an endoscopic mouthguard **[0005]** comprising: a bite block **(50, figure 3)** comprising a generally annular body **([0028], line 15)** adapted to be inserted into the mouth of a patient so as to maintain the upper and lower teeth of the patient in a spaced apart relationship **([0028], lines 17 - 18)** and define an endoscopic passage **(51, figure 3)** for introduction of an endoscope into the oral cavity of the patient **[0028], lines 18 – 20)**, the bite block including a gas delivery passage **(63, figure 5)** for delivery of a gas to the oral cavity of the patient; and a gas distribution manifold detachably engaged with said bite block **([0038], lines 18 -19)** the gas distribution manifold comprising: at least one inlet port for receiving gas from a gas supply **(66, figure 7)**; at least one nasal outlet port **(76, figure 7)** in fluid communication with the inlet port and adapted so as to direct gas to or toward the nasal passages of the patient; and an oral outlet port **(78, figure 7)** in fluid communication with the inlet port and configured such that when the gas distribution manifold is engaged with the bite block the oral outlet port is in fluid communication with the gas delivery passage, and when the gas distribution manifold is disengaged from the bite block and the bite block is removed from the mouth of the patient the oral outlet port is adapted to direct gas over or toward the mouth of the patient **(78, figure 7)**.

Regarding claim 2, Hickle discloses wherein the at least one nasal port **(76 figure 7)** comprises a pair of apertures arranged such that gas flowing from said apertures is directed toward the patient's nostrils from a position below the nose of the patient **([0039], lines 33 – 34)**.

Regarding claim 3, Hickle discloses wherein the gas distribution manifold further includes a pair of tubular portions each adapted to extend at least partly into each nostril of the patient and defining two nasal outlet ports **([0031], lines 5 – 12).**

Regarding claim 4, Hickle discloses wherein the at least one nasal port comprises a single elongate aperture, the single elongate aperture extending laterally to the patient in use such that gas is delivered to both nostrils of the patient **(76, figure 7).**

Regarding claim 5, Hickle discloses wherein the oral outlet port is a generally elongate aperture extending laterally relative to the patient in use **(78, figure 7).**

Regarding claim 6, Hickle discloses wherein the gas distribution manifold is detachably engaged with the bite block **([0038], lines 18 – 19)** by at least one frangible portion **([0039], lines 39 – 40)** extending between the bite block and the gas distribution manifold.

Regarding claim 7, Hickle discloses wherein the bite block and the gas distribution manifold each further include respective cooperating engagement means configured such that the gas distribution manifold is detachably and attachably engageable with the bite block **([0038], line 9).**

Regarding claim 8, Hickle discloses wherein the respective cooperating engagement means comprise compliant interlocking formations integrally formed with the gas distribution manifold and the bite block **([0039], lines 30 - 34).**

Regarding claim 9, Hickle discloses wherein the gas delivery passage comprises a first portion which is integrally formed with the annular body and defines a gas flow passage **(51, figure 3) & [0028], lines 18 – 20)** between the oral cavity and a

front region of the annular body, and a second portion (**52, figure 5**) which provides a connection between the oral outlet port and the first portion, said second portion having a distal end adapted to engage with the oral outlet port to provide gas communication between the oral outlet port and the gas delivery passage [**figure 7**].

Regarding claim 10, Hickle discloses wherein the gas delivery passage is of slot shape in cross-section with the longitudinal axis of the slot shape extending transverse to the axis of the annular body [**figure 5**].

Regarding claim 11, Hickle discloses wherein the gas delivery passage is integrally formed with the annular body and arranged such that when in use, the gas delivery passage is positioned superiorly to the endoscopic passage [**figure 5**].

Regarding claim 12, Hickle discloses herein the gas delivery passage terminates in a rearward facing opening which is arranged so as to deliver gas toward the rear of the oral cavity [**figure 5**].

Regarding claim 13, Hickle discloses wherein the gas distribution manifold further includes a tubular connector (**98, figure 4**) extending from the inlet port, said connector having a distal end engageable with a gas supply conduit [**figure 4**].

Regarding claim 14, Hickle discloses at least one obturator engagement formation integrally formed with the bite block, wherein the at least one obturator engagement formation provides an attachment point for an obturator member, the obturator member adapted to be used for depressing a patient's tongue to thereby provide improved access to the pharynx of the patient [**0036**].

Regarding claim 16, Hickle discloses wherein an outer surface of the annular body includes a contact portion adapted to be engaged by the teeth of the patient when the annular body is operatively positioned within the mouth of the patient **([0028], lines 25 – 29)**.

Regarding claim 17, Hickle discloses wherein a cushioning member is affixed to the contact portion so as to distribute the load imparted to the bite block by the patient's teeth **([0028], lines 25 – 36)**.

Regarding claim 18, Hickle discloses wherein the bite block includes an outer peripheral flange **(64, figure)** adapted to overlies the lips of the patient.

Regarding claim 21, Hickle discloses a gas distribution manifold **[figure 7]** for providing a gas to a patient, the gas distribution manifold comprising: at least one inlet port **(66, figure 7)** for receiving a gas from a gas supply; at least one nasal outlet port **(76, figure 7)** in fluid communication with the inlet port and adapted to direct gas to the nasal passages of the patient; and an oral outlet port **(78, figure 7)** in fluid communication with the inlet port and adapted to direct gas over or toward the mouth of the patient; said gas distribution manifold being detachably engageable with a bite block **([0038], lines 18 – 19)** having a gas delivery passage for delivery of a gas to the oral cavity of the patient; wherein the oral outlet port is configured such that when the gas distribution manifold is engaged with the bite block the oral outlet port is in fluid communication with the gas delivery passage **(78, figure 7)** of the bite block; and when the gas distribution manifold is disengaged from the bite block and the bite block is

removed from the mouth of the patient the oral outlet port is adapted to direct gas over or toward the mouth of the patient **(78, figure 7)**.

Regarding claim 22, a method of delivering a gas to the nasal passages and the mouth of a patient, wherein the gas is delivered to the nasal passages from below the nose and over or toward the mouth from above the mouth of the patient from a gas distribution manifold **([0039], lines 30 – 34)**; wherein the gas distribution manifold comprises: at least one inlet port **(66, figure 7)** for receiving gas from a gas supply; at least one nasal outlet port **(76, figure 7)** in fluid communication with the inlet port and adapted to direct gas to or toward the nasal passages of the patient; and an oral outlet port **(78, figure 7)** in fluid communication with the inlet port and configured to direct gas over or toward the mouth of the patient; said gas distribution manifold being detachably engageable with a bite block **([0038], lines 18 – 19)** having a gas delivery passage for delivery of a gas to the oral cavity of the patient; wherein the oral outlet port is configured such that when the gas distribution manifold is engaged with the bite block the oral outlet port is in fluid communication with the gas delivery passage of the bite block **(78, figure 7)**; and when the gas distribution manifold is disengaged from the bite block and the bite block is removed from the mouth of the patient the oral outlet port is adapted to direct gas over or toward the mouth of the patient **(78, figure 7)**.

Regarding claim 23, Hickle discloses wherein the gas is delivered to the patient during recovery from anaesthesia **[abstract[, lines 1 – 2]**.

Regarding claim 24, Hickle discloses wherein the gas is an oxygen rich gas **([0041], line 36)**.

Regarding claim 25, Hickle discloses an endoscopic mouthguard (**50, figure 3**) substantially as herein described with reference to the accompanying drawings.

Regarding claim 26, Hickle discloses a gas distribution manifold for providing a gas to a patient, substantially as herein described with reference to the accompanying drawings (**figure 7**).

Regarding claim 27, Hickle discloses a method of delivering a gas to the nasal passages and the mouth of a patient, substantially as herein described with reference to the accompanying drawings **[0040] & [0041], lines 1 – 9**.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 15, 19 & 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hickle Pub No. (US 2004/0129273 A1)**.

Regarding claim 15, Hickle discloses all of the claimed limitations above except wherein the endoscopic passage has a diameter of at least 20 mm so as to allow the passage of a 60Fr dilator there through.

However, Hickle teaches a bite portion **(60, figure 3)** may be constructed with any suitable dimensions, where bite portions may be enlarge for large scopes and tubes **([0028], lines 20 – 22)**.

It would have been obvious to one of ordinary skill in the art to make a bite block with dimensions large enough to accommodate large medical devices, as for example, endoscopes.

Regarding claim 19, Hickle discloses the claimed invention except that the bite block and the gas distribution manifold are formed from a resilient polymeric material, instead, Hickle discloses the bite block made from a flexible material by injection molding **([0028], lines 11 – 13)** is an equivalent structure known in the art. Therefore, because these two structures were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute one for another.

Regarding claim 20, Hickle discloses an attachment means located on the bite block **(53, figure 3)** for keeping the bite block stationary in a patient's mouth.

Hickle fails to disclose wherein the gas distribution manifold further includes an attachment means for securing the gas distribution manifold to the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to place an attachment means on the gas distribution manifold,

rather than on the bite block, since it has been held that rearranging parts of an invention involves only routine skill in the art. Furthermore, relocating the strap from the bite block to the gas distribution manifold does not change the functionality of the strap.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OPHELIA HAWTHORNE whose telephone number is (571) 270-3860. The examiner can normally be reached on Monday - Friday, 7:30 AM - 5:00 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ophelia Hawthorne/

Application/Control Number: 10/568,258

Page 11

Art Unit: 4148

Examiner, Art Unit 4148
/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4148